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The Accidental Administrative Law of the Medicare Program

Eleanor D. Kinney, JD, MPH*

INTRODUCTION

On July 30, 1965, President Lyndon B. Johnson signed the Social Security Amendments of 1965, which established the Medicare and Medicaid programs.¹ This legislation was the result of multiple efforts by the Democratic Party to bring government sponsored health insurance coverage to the American people. The legislation, by today's standards, was simple. The *Statutes at Large* version of the legislation is less than 30,000 words.

Today, the Medicare program is massive. The number of Medicare beneficiaries increased from 19.1 million in 1966 to about 52.3 million in 2013, a 174 percent increase.² The Medicare program now partially funds and regulates one fifth of the US health care sector, which constituted over 17.2 percent of the US economy in 2012, as measured by percentage of GDP.³

Today, the Medicare program is governed by a complex web of legislative rules, interpretive rules and manuals, policy guidance and computer programs which guide a host of decisions on issues related to the operation of the Medicare program. The Medicare program also maintains multiple appeals processes for beneficiaries, physicians, institutional providers, suppliers, and contractors over a variety of issues including payment amounts to providers, determinations of status for Medicare administrative contractors, and coverage appeals of Medicare beneficiaries. Medicare also has vigorous civil and criminal enforcement programs for reducing fraud and abuse.

This Article traces the evolution of administrative procedures for policy-making and adjudication in the Medicare program since its inauguration. Part II of

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1. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. §§ 1395, 1396 (2012)).

2. Ctrs. for Medicare & Medicaid Servs. *CMS Statistics 2013*, U.S. DEP'T HEALTH & HUM. SERVS. (2014), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS_Stats_2013_final.pdf.

3. Ctrs. for Medicare & Medicaid Servs., *National Health Expenditures 2012 Highlights*, U.S. DEP'T HEALTH & HUM. SERVS. (2013), <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>.

this article provides background information on the Medicare program that is relevant to Medicare's administrative functions. Part III traces the evolution of administrative procedures for policy-making and adjudication in the Medicare program since its inauguration. Part IV addresses how some Medicare appeals systems are not meeting the needs of the program or its beneficiaries nor of its providers, suppliers and contractors. Finally, Part V will explore the collaborative approaches to policy-making that have occurred since 2000 and, in particular, in the Patient Protection and Affordable Care Act (ACA),⁴ as amended by the Health Care and Education Reconciliation Act of 2010.⁵

I. THE MEDICARE PROGRAM

The architects of the Medicare program saw themselves as designing a government benefit program in the Social Security system. The original Medicare program contained two parts. Part A, Hospital Insurance for the Aged and Disabled, covers hospital and related services such as skilled nursing and home health care.⁶ Part B, Supplementary Medical Insurance, covers physician and other outpatient services.⁷ Part A and Part B together are called "Original Medicare" or "Fee-for-Service" Medicare. Pursuant to contract, Medicare administrative contractors handle claims and pay providers as well as adjudicate appeals and make program policy.⁸ Congress later added a managed care plan option in 1997 in a new Part C of the Medicare statute,⁹ which was enhanced in the Medicare Modernization Act of 2003.¹⁰ Also in this legislation, Congress added a voluntary prescription drug benefit in Part D of the Medicare statute.¹¹ The Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) administers the Medicare program.¹² Figure 1 summarizes the Parts of the Medicare program and the benefits they cover.

4. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

5. Health Care and Education Reconciliation Act (HCERA) of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

6. Codified as amended at 42 U.S.C. §§ 1395c-i (2012).

7. Codified as amended at 42 U.S.C. §§ 1395j to 1395w-4 (2012).

8. 42 U.S.C. §§ 1395h, 1395u (2012).

9. Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275 (codified as amended at 42 U.S.C. § 1395w-21 (2012)).

10. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, §§ 201-241, 117 Stat. 2066, 2176-221 (2003) (codified as amended at 42 U.S.C. § 1395w-21 (2012)).

11. *Id.* § 101 (codified as amended at 42 U.S.C. § 1395w-101 (2012)).

12. HHS was formerly the U.S. Department of Health, Education and Welfare (HEW). CMS was formerly the Health Care Financing Administration (HCFA).

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FIGURE 1¹³: THE PARTS OF THE MEDICARE STATUTE ESTABLISHING PARTS OF THE MEDICARE PROGRAM

<p align="center">Part A—Hospital Insurance Benefits for Aged and Disabled (§§ 1395c-1395j5)</p> <p>Part A covers most medically necessary hospital, skilled nursing facility, home health and hospice care. Part A is financed by a payroll tax and is free to those eligible for Social Security.</p>
<p align="center">Part B—Supplementary Medical Insurance Benefits for Aged and Disabled (§§ 1395j-1395w5)</p> <p>Part B covers most medically necessary doctors' services, preventive care, durable medical equipment, hospital outpatient services, laboratory tests, x-rays, mental health care, and some home health and ambulance services. Beneficiaries pay a monthly premium for this coverage.</p>
<p align="center">Part C—Medicare Choice Program* (§§ 1395w21-1395w29)</p> <p>Part C is not a separate benefit but a program that allows private health insurance companies to provide Medicare benefits. These private health plans are called Medicare Advantage plans. Medicare Advantage plans must offer at least the same benefits as Original Medicare (those covered under Parts A and B) but can do so with different rules, costs and coverage restrictions. Part D prescription drugs can be included in Medicare Advantage plans. Many different kinds of Medicare Advantage plans are available. Beneficiaries may pay a monthly premium for this coverage, in addition to their Part B premium.</p>
<p align="center">Part D—Voluntary Prescription Drug Benefit Program (§§ 1395w101-1395w154)</p> <p>Part D covers outpatient prescription drug coverage. Part D is provided only through private insurance companies that have contracts with the government. As per Part C, Medicare Advantage plans can offer Part D prescription drug benefits.</p>
<p align="center">Part E—Miscellaneous Provisions (§§ 1395x-1395kkk1)</p> <p>Part E contains a variety of provisions, such as definitions, that apply to all parts of the Medicare program.</p> <p>*The Medicare Modernization Act changed the name of this program to the "Medicare Advantage" program but the title of Part C was never changed, and reflects the name of the 1997 program.</p>

13. *What does Medicare cover (Parts A, B, C and D)?*, MEDICARE INTERACTIVE (2014), http://www.medicareinteractive.org/page2.php?topic=counselor&page=script&script_id=214 (last visited Dec. 14, 2014).

Initially, Medicare paid institutional providers their reasonable costs and physician and other outpatient providers their usual and customary charge.¹⁴ The only stipulation was that costs and charges be “reasonable and necessary.”¹⁵ These payment methods, which gave control of payment amounts with providers, generated inflation in Medicare program expenditures. Expenditures grew from 7.5 billion dollars in 1970 to an estimated 572.9 billion dollars in 2010. In 2013, Medicare program costs were about 500 billion dollars or roughly 14 percent of the federal budget.¹⁶

A. The Medicare Program as Benefit Program

Congress designed the Medicare program as a benefit program and located the program in the Social Security system. Historically, federal benefit programs provide funds for certain categories of people to achieve social goals.¹⁷ The federal government defines “assistance” or “benefits” as follows:

“Assistance” or “benefits” refers to the transfer of money, property, services, or anything of value, the principal purpose of which is to accomplish a public purpose of support or stimulation authorized by Federal statute. Assistance includes, but is not limited to grants, loans, loan guarantees, scholarships, mortgage loans, insurance, and other types of financial assistance, including cooperative agreements; property, technical assistance, counseling, statistical, and other expert information; and service activities of regulatory agencies. It does not include the provision of conventional public information services.¹⁸

The Medicare program falls within this definition of a “benefit” or “assistance.” Medicare is essentially “insurance,” a product included in the definitional list.

Given that the Medicare program was essentially a benefit program, the architects of the Medicare program in 1965 were not inclined to open up administrative processes for Medicare beneficiaries and particularly Medicare providers, suppliers and other contractors to challenge decisions and policies of the Medicare program. Because Medicare was a benefit program, as discussed in Part III.A, they were not required to do so under the procedural due process

14. Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 291 (codified as amended at 42 U.S.C. §§ 1395(f)(b), 1395x(v), 1395l(a) (2012)).

15. *Id.* § 1862 (codified as amended at 42 U.S.C. § 1395y(a)(1) (2012)).

16. *Id.*

17. See JERRY L. MASHAW, CREATING THE ADMINISTRATIVE CONSTITUTION: THE LOST ONE HUNDRED YEARS OF AMERICAN ADMINISTRATIVE LAW (2012).

18. *CFDA Overview*, CATALOGUE OF FED. DOMESTIC ASSISTANCE, <https://www.cfda.gov/?s=generalinfo&mode=list&tab=list> (last visited Nov. 17, 2014).

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jurisprudence at the time.¹⁹

However, there is one major distinction between Medicare and other programs that provide health care items or services and many other federal benefit programs. Specifically, Medicare must purchase covered items or services from independent vendors whereas other benefit programs generally distribute cash to program beneficiaries. This fact, as discussed below, means that Medicare eventually had to become a procurement program and finally a regulatory program. Because of the inflationary costs and charges presented by providers and suppliers for compensation, the Medicare program had to resort to rate regulation to control Medicare expenditures.²⁰

B. The Medicare Program as Procurement Program

Medicare had to become a procurement program and face all the problems exhibited in procurement programs—profit-seeking and/or fraudulent vendors and cost and volume inflation. Today, there are more recoveries under President Lincoln’s False Claims Act²¹ for the Medicare and Medicaid programs than government procurement for the defense department. In 2013, recoveries for health care fraud were \$2.6 billion compared to procurement fraud (related primarily to defense contracts) of \$890 million.²² In his satirical account of the Medicare program, David Hyman explains the process:

Congress initially failed to appreciate how avarice would affect the Medicare program. When Medicare was enacted in 1965, a single provision prohibited making false statements to secure reimbursement. Matters did not remain in this pristine form for long, as the Medicare honeypot quickly attracted the more feloniously inclined members of the profession. In relatively short order, there developed a complicated interlocking array of health care-specific civil, criminal, and administrative anti-fraud laws and regulations enacted by the states and the federal government, along with multiple levels of investigative and enforcement agencies.²³

The only anti-fraud provision pertaining to the Medicare program was in the Social Security Act of 1935 prohibiting false statements in connection with seeking

19. See *infra* notes 33-48 and accompanying text.

20. See *infra* notes 131-39 and accompanying text.

21. False Claims Act, ch. 67, 12 Stat. 696 (1863) (codified as amended at 31 U.S.C. §§ 3729-33 (2012)).

22. Office of Pub. Affairs, *Press Release: Justice Department Recovers \$3.8 Billion from False Claims Act Cases in Fiscal Year 2013*, U.S. DEP’T JUSTICE (Dec. 20, 2013), <http://www.justice.gov/opa/pr/justice-department-recovers-38-billion-false-claims-act-cases-fiscal-year-2013>.

23. DAVID HYMAN, *MEDICARE MEETS MEPHISTOPHELES* 31 (2005).

reimbursement for services.²⁴ In the Social Security Amendment of 1972, Congress established tougher authorities for punishing fraudulent acts and false statements, the first of many statutes to enhance Medicare fraud and abuse enforcement.²⁵ Providers and suppliers disciplined for fraud and abuse infractions have rights to administrative and judicial review before the Civil Remedies Division of the HHS Department Appeals Board (DAB).²⁶

In 1997, Congress accorded HHS Inspector General (OIG) authority to issue advisory opinions about the application of OIG's fraud and abuse authorities to a requesting party's existing or proposed business arrangement.²⁷ Advisory opinions are widely used in regulatory agencies to facilitate compliance. With this authority, OIG can behave much like other procurement agencies that give guidance to vendors and other regulated parties about the legality of their proposed transactions.

The OIG, established in 1976,²⁸ has not experienced the difficulties with administrative law that CMS and previously Health Care Financing Administration (HCFA) have. A major reason for this phenomenon is because OIG was established with an exceptionally clear purpose: to conduct audits and investigations of department programs as an independent unit within HHS.²⁹

24. Social Security Act of 1935, Pub. L. No. 74-271, § 209, 49 Stat. 620, 625. The provision stated: "Whoever in any application for any payment under this title makes any false statement as to any material fact, knowing such statement to be false, shall be fined not more than \$1,000 or imprisoned for not more than one year, or both." *Id.*

25. Social Security Amendments of 1972, Pub. L. No. 92-602, § 242, 86 Stat. 1329, 1419 (codified as amended at 42 U.S.C. § 1395ii (2012)).

26. *The Civil Remedies Division*, U.S. DEP'T HEALTH & HUM. SERVS., <http://www.hhs.gov/dab/divisions/civil/> (last visited Nov. 17, 2014).

27. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000 (codified as amended at 42 U.S.C. § 1320a-7d (2012)).

28. HEW Inspector General Act of 1976, Pub. L. No. 94-505, §§ 201-207, 90 Stat. 2429, 2429-34, *repealed by* Inspector General Amendments of 1988, Pub. L. No. 100-504, §102(e)(2), 102 Stat. 2515, 2517. The functions of the HEW Inspector General were transferred by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101; *see* James R. Naughton, *The Origin and Implementation of the Inspector General Act*, 47 GOV. ACCT. J. 12 (1998); Genevieve Nowolinski, *A Brief History of the HHS Office of Inspector General*, U.S. DEP'T HEALTH & HUM. SERVS. (2001), <http://www.kinneyassoc.com/MedEdHistory/historyhhoig.pdf>.

29. The original statute creating the OIG for HEW provided:

In order to create an independent and objective unit--

- (1) to conduct and supervise audits and investigations relating to programs and operations of the Department of Health, Education, and Welfare;
- (2) to provide leadership and coordination and recommend policies for activities designed (A) to promote economy and efficiency in the administration of, and (B) to prevent and detect fraud and abuse in, such programs and operations; and
- (3) provide a means for keeping the Secretary and the Congress fully and currently informed about problems and deficiencies relating to the administration of such programs and operations and the necessity for and progress of corrective action;

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Consequently, the Medicare program's experience with fraud and abuse control will not be discussed further in this article.

C. The Medicare Program as Regulatory Program

Congress did not intend for Medicare to regulate the American health care sector. Medicare was intended to behave like any other federal benefit program and simply pay claims on a retrospective basis. Indeed, the first section of the Medicare statute states:

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.³⁰

However, as Medicare responded to escalating costs, the program transformed from a passive distributor of benefits to a major regulator of the health care sector. In the Social Security Amendments of 1972, Congress enacted several regulatory programs to reduce costs.³¹ These programs included limits on payment of institutional provider costs,³² limits on physician charges,³³ limits on payments for unapproved capital expenditures,³⁴ and establishment of professional standards review organizations for utilization review of hospital care.³⁵

Throughout this transformation, and with the mindset of a benefits program, Medicare policy-makers wrestled with associated administrative law issues with a poor sense of how administrative law functions in a regulatory context. The result of their deliberations was the development of unanticipated and often unique procedures for making rules and policy, enforcing regulatory requirements and adjudicating disputes.

II. THE EVOLUTION OF MEDICARE ADMINISTRATIVE LAW

To understand the accidental nature of the administrative law of the Medicare, a historical analysis is appropriate. The original Medicare program was quite

there is hereby established in the Department of Health, Education, and Welfare an Office of Inspector General.

HEW Inspector General Act of 1976 § 201 (codified as amended 42 U.S.C. § 3521 (2012)).

30. 42 U.S.C. § 1395 (2012).

31. Social Security Amendments of 1972, Pub. L. No. 92-602, 86 Stat. 1329 (codified as amended in scattered sections of 42 U.S.C.).

32. *Id.* § 223 (codified as amended at 42 U.S.C. § 1395x(v)(1) (2012)).

33. *Id.* § 224 (codified as amended at 42 U.S.C. § 1395u(b) (2012)).

34. *Id.* § 221 (codified as amended at 42 U.S.C. § 1301 (2012)).

35. *Id.* § 249F (codified as amended at 42 U.S.C. § 1320c (2012)).

different than the Medicare program today. Further, the development of the Medicare program coincided with major changes in federal administrative law in the postwar period.

A. Administrative Law Provisions in the Social Security Amendments of 1965

In 1946, to clarify agency procedure that had grown idiosyncratically during the New Deal and World War II, Congress enacted the Administrative Procedure Act.³⁶ The Administrative Procedure Act targeted regulatory programs that affected parties' life, liberty and property. At the time, administrative law did not recognize government benefits as property subject to constitutional protection.

The Administrative Procedure Act provided that rules for government benefits need not be made pursuant to section 553 rule-making procedures.³⁷ Following a recommendation of the Administrative Conference of the United States,³⁸ HEW agreed to use notice-and-comment rulemaking when promulgating a legislative-type rule for its programs.³⁹ However, this exemption is still technically in effect. Further, the federal Administrative Procedure Act of 1946 contained only formal, trial-type adjudication procedures only for disputes over recognized property and liberty rights.⁴⁰

During the 1950s and early 1960s, in large part due to a reaction to the activities of Senator Joe McCarthy and the House Un-American Activities Committee, legal scholars and advocates, as well as the Supreme Court of the United States,⁴¹ were reexamining the jurisprudence of the procedural due process doctrine.⁴² In 1964, Yale law professor Charles A. Reich articulated a new conception of government largess as protected property under the Due Process Clause of the Fifth Amendment.⁴³

The Supreme Court eventually adopted this conception of property in its 1970

36. Administrative Procedure Act (APA), Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended in scattered sections of 5 U.S.C.).

37. *Id.* § 4.

38. § 305.69-8 Elimination of Certain Exemptions from the APA Rulemaking Requirements, 38 Fed. Reg. 19,784-85 (July 23, 1973).

39. Public Participation in Rulemaking, 36 Fed. Reg. 2532 (Feb. 5, 1971).

40. *See id.* § 5.

41. *See, e.g.,* Cafeteria and Restaurant Workers Union, Local 473 v. McElroy, 367 U.S. 886 (1961); Barsky v. Bd. of Regents, 347 U.S. 442 (1954); Joint Anti-Fascist Refugee Comm. v. McGrath, 341 U.S. 123 (1951).

42. *See* STUART BANNER, AMERICAN PROPERTY (2011); Elizabeth Bussiere, *The "New Property" Theory of Welfare Rights: Promises and Pitfalls*, 13 GOOD SOC'Y 1 (2004); Robert J. Harris, *The Impact of the Cold War upon Civil Liberties*, 18 J. POL. 3 (1956).

43. Charles A. Reich, *Individual Rights and Social Welfare: The Emerging Legal Issues*, 74 YALE L.J. 1245 (1965); Charles A. Reich, *The New Property*, 73 YALE L.J. 733 (1964).

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decision, *Goldberg v. Kelly*.⁴⁴ In *Goldberg*, the Court recognized welfare government benefits as protected property and even quoted Reich's article in footnote 8 of the decision: "It may be realistic today to regard welfare entitlements as more like 'property' than a 'gratuity.'"⁴⁵

Goldberg represented the high water mark in procedural due process protections accorded to individuals with grievances over prospective government action.⁴⁶ The Supreme Court later moved away from requiring a pre-termination evidentiary hearing in benefits cases.⁴⁷ Over the years, procedural due process rights have been diluted further.⁴⁸

However, in the early 1970s, *Goldberg v. Kelly* signaled a constitutional preference for evidentiary hearings where procedural due process was implicated. Thus, as Congress added appeals procedures for providers with the establishment of the Provider Reimbursement Review Board, it adopted trial-type procedures for institutional provider payment disputes.⁴⁹ Similarly, when Congress reestablished administrative and judicial review in 1986 for beneficiaries and their professional providers and suppliers under Part B of the Medicare program, it adopted the model of evidentiary hearings for these appeals.⁵⁰

At the time that Congress enacted the Social Security Amendments of 1965, *Goldberg v. Kelly*, and thus the notion that procedural due process rights should be granted for disputes over federal benefits, was in the distance. The Medicare statute only provided for appeals of Medicare beneficiaries under section 1869 of the Social Security Amendments of 1965,⁵¹ and the contractors that administered the program on behalf of HEW.⁵²

44. 397 U.S. 254 (1970).

45. 397 U.S. at 262, n.8 (citing Charles Reich, *Individual Rights and Social Welfare*, *supra* note 43, at 1255).

46. William Van Alstyne, "Cracks in the New Property": *Adjudicative Due Process in the Administrative State*, 62 CORNELL L. REV. 445 (1977); Henry J. Friendly, *Some Kind of Hearing*, 123 U. PA. L. REV. 1267 (1975).

47. See *Cleveland Bd. of Education v. Loudermill*, 470 U.S. 532 (1985); *Mathews v. Eldridge*, 424 U.S. 319 (1976).

48. See Richard J. Pierce, Jr., *The Due Process Counterrevolution of the 1990s?*, 96 COLUM. L. REV. 1973 (1996); Sidney A. Shapiro & Richard E. Levy, *Government Benefits and the Rule of Law: Toward a Standards-Based Theory of Due Process*, 57 ADMIN. L. REV. 107 (2005).

49. Social Security Amendments of 1972, Pub. L. No. 92-602, § 243(a), 86 Stat. 1329, 1420-22 (codified as amended at 42 U.S.C. § 1395oo (2012)).

50. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a), 100 Stat. 1874, 2037-38, (codified as amended at 42 U.S.C. § 1395ff(b) (2012)).

51. Social Security Amendments of 1965, Pub. L. No. 89-97, § 1869, 79 Stat. 286, 33 (codified as amended at 42 U.S.C. § 405 (2012)).

52. Section 1869 provided:

(a) The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A, shall be made by the Secretary in accordance with regulations prescribed by him.

Further, there was no requirement upon HEW, in managing Medicare benefits, to engage in rulemaking procedures to promulgate effective rules under the Administrative Procedures Act. Specifically, section 553(a)(2) of the Administrative Procedure Act exempts rules from rulemaking procedures that pertain to “a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.”⁵³ In 1972, the Administrative Conference of the United States (ACUS) recommended elimination of this exemption.⁵⁴ In a 1972 notice, HEW agreed to follow the ACUS recommendation and use notice-and-comment rulemaking when promulgating a legislative-type rule for its programs.⁵⁵ However, CMS is technically not bound to this commitment.

The Social Security Amendments of 1965 contained three provisions pertaining to administrative law issues. One section addressed the administration of the Medicare program.⁵⁶ Another two-sentence section authorized the promulgation of regulations.⁵⁷ A third section authorized appeals of decisions on

(b) Any individual dissatisfied with any determination under subsection (a) as to entitlement under part A or part B, or as to amount of benefits under part A where the matter in controversy is \$100 or more, shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and, in the case of a determination as to entitlement or as to amount of benefits where the amount in controversy is \$1,000 or more, to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

(c) Any institution or agency dissatisfied with any determination by the Secretary that it is not a provider of services, or with any determination described in section 1866(b)(2), shall be entitled to a hearing thereon by the Secretary (after reasonable notice and opportunity for hearing) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

Id. § 1869 (codified as amended at 42 U.S.C. § 1395ff (2012)).

53. 5 U.S.C. § 553(a)(2) (2012).

54. Elimination of Certain Exemptions from the APA Rulemaking Requirements, ACUS Recommendation No. 69-8, 38 Federal Register 19784 (July 23, 1973).

55. Public Participation in Rulemaking, HEW Notice, 36 Federal Register 2532 (Feb. 5, 1971).

56. Section 1874, Administration, provided:

(a) Except as otherwise provided in this title, the insurance programs established by this title shall be administered by the Secretary. The Secretary may perform any of his functions under this title directly, or by contract providing for payment in advance or by way of reimbursement, and in such installments, as the Secretary may deem necessary.

(b) The Secretary may contract with any person, agency, or institution to secure on a reimbursable basis such special data, actuarial information, and other information as may be necessary in the carrying out of his functions under this title.

Id. § 1874 (codified as amended at 42 U.S.C. § 1395kk (2012)).

57. Section 1871 provided authority for the promulgation of regulations: “The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title. When used in this title, the term ‘regulations’ means, unless the context

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claims under the Social Security Act.⁵⁸

B. Rule and Policy-Making under the Medicare Program in the Twentieth Century

The evolution of Medicare rule and policy-making process is convoluted. In the early years of the Medicare program, policy-making was quite informal and decentralized. For example, the original policy on hospital payment was based on principles of cost reimbursement from the American Hospital Association (AHA) and Blue Cross and Blue Shield Association.⁵⁹ The local contractor administering the Medicare program made coverage and other program policy.

In its early years, HCFA would often issue major policy with little notice in inaccessible manuals and other guidance documents. In the mid-1980s, Congress enacted stricter requirements for promulgating substantive Medicare policy.⁶⁰ In later years, CMS promulgated interim final rules that have immediate effect with an opportunity to comment. In the Medicare Modernization Act, Congress imposed a timeline and process through which interim final regulations would convert to final rules or become invalid.⁶¹

1. Medicare Coverage Policy-Making

In the early 1980s, HCFA realized that Medicare was paying for heart transplants in some states but not in others, and thus issued a ruling denying coverage of heart transplants on a national basis.⁶² It later issued a new ruling covering heart transplants.⁶³ Initially, the Medicare contractors handling claims on a state-wide basis were to make local coverage decisions and did so for the first

otherwise requires, regulations prescribed by the Secretary.” *Id.* § 1871 (codified as amended at 42 U.S.C. § 1395hh (2012)).

58. Social Security Amendments of 1965, Pub. L. No. 89-97, § 1869, 79 Stat. 286, 330 (codified as amended at 42 U.S.C. § 1395ff (2012)). See *supra* note 51.

59. See JUDITH M. FEDER, *MEDICARE: THE POLITICS OF FEDERAL HOSPITAL INSURANCE* 54-80 (1977); SYLVIA A. LAW, *BLUE CROSS: WHAT WENT WRONG?* 59-65 (2d ed. 1976); HERMAN M. SOMERS & ANNE R. SOMERS, *MEDICARE AND THE HOSPITALS* 154-58 (1967).

60. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, §4035(b)-(c), 101 Stat. 1330, 1330-78 (codified as amended at § 1395hh(a)(2)-hh(c) (2012)).

61. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, § 902, 117 Stat. 2066, 2375 (codified as amended at 42 U.S.C. § 1395hh(a) (2012)); see Timothy S. Jost, *The Most Important Health Care Legislation of the Millennium (So Far): The Medicare Modernization Act*, 5 YALE J. HEALTH POL’Y, L. & ETHICS 437, 437-49 (2005).

62. Exclusion of Heart Transplantation Procedures from Medicare Coverage, 45 Fed. Reg. 52,296 (Aug. 6, 1980); see Ward Casscells, *Heart Transplantation: Recent Policy Developments*, 315 NEW ENG. J. MED. 1365 (1986).

63. Criteria for Medicare Coverage of Heart Transplants, 52 Fed. Reg. 10,933, 10,935 (Apr. 6, 1987) (notice of administrative ruling); see Gregory de Lissovoy, *Medicare and Heart Transplants: Will Lightning Strike Twice?*, 7 HEALTH AFF. 61 (1988).

fifteen years of the Medicare program.

However, with the heart transplant controversy and the burgeoning advances in medical technology, coverage of expensive new technologies surfaced as an important issue for Medicare policy makers. This was spurred in part by the Medicare program's infusion of money into the health care sector. The medical device industry was very interested in Medicare coverage policy-making, especially because, as of 1976, manufacturers had to get the approval of the Food and Drug Administration under the Medical Device Amendments of 1976 in order to market their products in the United States.⁶⁴

In the early 1980s, a committee of physicians who worked for HCFA made national coverage decisions in a stunningly secretive process that purposely excluded any participation or input from vitally interested medical device manufacturers. HCFA justified its secretive process by saying that HCFA has no obligation to medical device manufacturers to let them participate in the coverage decision-making process.⁶⁵ Their obligation was strictly to Medicare beneficiaries. In *TAP Pharmaceuticals v. U.S. Department of Health and Human Services*,⁶⁶ the United States Court of Appeals for the Fourth Circuit affirmed a lower court ruling that a pharmaceutical manufacturer challenging a Medicare policy regarding the price of a drug did not fall within the "zone of interests" protected by the Medicare statute.⁶⁷ This decision on standing reinforced the Medicare program's conception of itself as answerable primarily to Medicare beneficiaries.

In the 1980s, the Administrative Conference of the United States⁶⁸ and the American Bar Association,⁶⁹ among others, called for more regularity and transparency in Medicare coverage policy and decision-making processes. As part of a settlement of a lawsuit,⁷⁰ HCFA developed public procedures for making coverage policy but the effort was derailed over a proposed criterion of cost effectiveness.⁷¹ Indeed, neither HCFA nor CMS has promulgated a final rule due

64. Medical Device Amendments (MDA) of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 301 (2012)).

65. See Darrel J. Grinstead, *Evolution of the Medicare Coverage Policy-Making Process*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS 1, 6 (Eleanor D. Kinney ed., 2002).

66. 163 F.3d 199 (4th Cir. 1998).

67. *Id.* at 200.

68. Recommendation 87-8, National Coverage Determinations Under the Medicare Program, 1 C.F.R. § 305.87-8 (1987); Recommendation 86-5, Medicare Appeals, 1 C.F.R. § 305.86-5 (1986).

69. AM. BAR ASS'N, RECOMMENDATIONS ON MEDICARE PROCEDURES BY THE ABA HOUSE OF DELEGATES (Aug. 1988).

70. *Jameson v. Bowen*, No. CV-F-8-547, 1987 WL 108970 (E.D. Cal. Feb. 20, 1987).

71. Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302 (Jan. 30, 1989) (to be codified at 42 C.F.R. pts. 400, 405); see Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560 (Apr. 29, 1987).

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to the opposition of medical device industry over cost effectiveness.⁷²

HCFA did establish an internal policy-making process with its Technical Advisory Committee, comprised of medical directors from Medicare contractors and representatives of other interested federal agencies.⁷³ In 1998, the U.S. General Accounting Office (GAO) found that the Technical Advisory Committee violated the Federal Advisory Committee Act.⁷⁴ In response to this report, HCFA agreed to reformulate the committee's composition of only federal officials and develop a new compliant advisory committee in the future. The GAO agreed to this approach.⁷⁵

The medical device industry was completely frustrated with the coverage policy and decision-making process. The medical device industry is huge and economically important. To illustrate, 70 percent of all surgeries in the U.S. involve an implant, which is a medical device, and these implants account for up to 70 percent of the total cost of surgical care.⁷⁶ An industry this large and so dependent on Medicare reimbursement for its success was clearly going to marshal the lobbying effort to crack open an essentially secret process for regulatory decision-making.

In 1999, attorneys for the Indiana Medical Device Manufacturers Council petitioned HCFA for a rule to establish a transparent coverage decision-making process.⁷⁷ The petition and other lobbying efforts resulted in congressional hearings,⁷⁸ and subsequent legislative reforms. CMS did issue a notice establishing a process for making national coverage decisions.⁷⁹ However, it generally stated

72. See Susan B. Foote, *Why Medicare Cannot Promulgate a National Coverage Rule: A Case of Regula Mortis*, 27 J. HEALTH POL. POL'Y & L. 707 (2002); Sean R. Tunis, *Why Medicare Has Not Established Criteria for Coverage Decisions*, 350 NEW ENG. J. MED. 2196 (2004).

73. *Issues Relating to Medicare's Coverage Policy: Hearing Before the Health Subcomm. of the H. Comm. on Ways and Means*, 105th Cong. 12 (1997) (statement of Hon. Bruce C. Vladeck, Administrator, Health Care Financing Administration); see Grinstead, *supra* note 65, at 14.

74. *Advisory Committee Act: Violation by the Health Care Financing Administration*, U.S. GEN. ACCT. OFF. 1-2 (1998), <http://www.gao.gov/decisions/archive/278940.pdf>.

75. Letter from Barry R. Bedrick, Assoc. Gen. Counsel, U.S. Gen. Accounting Office, to Hon. Bill Thomas, Chairman, Subcomm. on Health, Comm. on Ways and Means, on the Advisory Committee Act: Violation by Health Care Financing Administration (Jan. 13, 1998), <http://www.gao.gov/decisions/archive/278940.pdf>.

76. Prakash Patel, *A Disrupted Landscape: The New Medical Device Industry*, BECKER'S HOSP. REV. (Oct. 16, 2013), <http://www.beckershospitalreview.com/news-analysis/a-disrupted-landscape-the-new-medical-device-industry.html>.

77. Citizen's Petition from Bradley Merrill Thompson, Baker & Daniels, to Nancy-Ann Min DeParle, Adm'r, Health Care Fin. Admin. (Mar. 4, 1998) (on file with author).

78. *The Medicare Coverage Decisions and Beneficiary Appeals: Hearings Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 106th Cong. 21-128 (1999); *Patient Appeals in Health Care: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 105th Cong. 4-76 (1998).

79. Medicare Program; Procedures for Making National Coverage Decisions, 64 Federal Register 22,619 (Apr. 27, 1999).

HCFA's commitment to provide notice of its activities regarding national coverage determinations but offered little with respect to active participation in the process. The notice did not satisfy manufacturers who continued to press for reforms.

In 2000, a Republican Congress established statutory Medicare coverage policy and decision-making procedures.⁸⁰ These requirements intended to make the coverage policy-making process more transparent to device manufacturers and other interested parties. In the MMA of 2003, Congress made major changes, including stricter deadlines for the national coverage policy-making process.⁸¹

The history of coverage policy-making is exemplary of HCFA's not understanding itself as a regulatory program. CMS did not appreciate the interests of device manufacturers and perceived its only obligation in the coverage decision-making process as protecting beneficiaries from unreasonable, unnecessary and unduly costly health care services. At every turn in the development of the Medicare coverage decision-making and appeals processes during the last century, CMS resisted opening the processes in any way to accommodate the interest of medical device manufacturers.

In recent years, CMS has become much more open in its coverage policy-making process and today, coverage policy-making is far more collaborative. CMS publishes its deliberations on a public website,⁸² and the statutory policy process accords multiple opportunities for input and participation of stakeholders.

2. Medicare Payment Policy-Making

Over time, cost containment became more and more imperative as Medicare expenditures escalated. Congress enacted numerous payment reforms that were increasingly regulatory in scope and intensity. In the Social Security Amendments of 1972, Congress also authorized HEW to conduct demonstrations of different ways Medicare could pay for inpatient hospital and skilled nursing care services.⁸³ Developed at Yale University,⁸⁴ and tested in New Jersey,⁸⁵ HCFA developed a

80. Consolidated Appropriations – FY 2001, Pub. L. No. 106-554, § 522(a), 114 Stat. 2763, 2763H-72 to -85 (2000) (codified as amended at 42 U.S.C. § 1395y(a) (2012)).

81. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, § 731(a)(1), 117 Stat. 2066, 2349 (codified as amended at 42 U.S.C. § 1395y (2012)).

82. *Medicare Coverage Center*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html> (last visited Nov. 17, 2014).

83. Social Security Amendments of 1972, Pub. L. No. 92-602, § 222, 86 Stat. 1329, 1390 (codified as amended at 42 U.S.C. § 1395b-1 note (2012)).

84. John D. Thompson, *The History of the Development of DRGs, in COMPELLED BY DATA: JOHN D. THOMPSON—NURSE, HEALTH SERVICES RESEARCHER AND HEALTH ADMINISTRATION EDUCATOR* 71 (William D. White ed., 2003).

85. William C. Hsiao et al., *Lessons of the New Jersey DRG Payment System*, 5 HEALTH AFF. 32 (1986).

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new prospective payment system for inpatient hospitals based on Diagnosis Related Groups (DRGs). DRGs are units of a classification system that group similar clinical conditions and resources furnished by the hospital during a patient's stay.⁸⁶

Following the HHS proposal for a prospective payment system based on DRGs,⁸⁷ Congress adopted the prospective payment system for acute care inpatient hospitals in the spring of 1983.⁸⁸ Under this payment system, the Medicare program pays acute care hospitals a fixed price, adjusted for geographic and wage cost differences, for each Medicare case based on the DRG in which the patient's particular condition falls.⁸⁹

In 1989, Congress enacted a revised payment system for physician services that paid physicians based on the time and resources involved in treating specific conditions.⁹⁰ Congress enhanced the system in 1990.⁹¹ Congress replaced the charge-based fee schedule with the Resource Based Relative Value Scale (RBRVS). The RBRVS is based on relative value units (RVUs) for three cost components of medical care—physicians' work effort, physicians' practice expenses, and malpractice liability insurance expenses.

Historically, HCFA was not transparent in promulgating payment policy. One reason for this lack of transparency was that, ostensibly, the insurance companies that administered the Medicare program pursuant to contract made payment policy on a local basis. To address the lack of transparency in payment policy-making, Congress required HCFA to publish and make available manual provisions and other guidance every three months.⁹² HCFA also applied rules retroactively and inappropriately, according to the Supreme Court.⁹³

In adopting the inpatient hospital prospective payment system, Congress was concerned about HCFA overreaching in setting payment rates. The AHA urged

86. Ctrs. for Medicare & Medicaid Servs., *Acute Care Hospital Inpatient Prospective Payment System*, U.S. DEP'T HEALTH & HUM. SERVS. (2013), <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymntSysfctsht.pdf>; *Acute Inpatient PPS*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/AcuteInpatientPPS> (last visited Nov. 17, 2014).

87. *Hospital Prospective Payment for Medicare: Report to Congress Required by the Tax Equity And Fiscal Responsibility Act of 1982*, U.S. DEP'T HEALTH & HUM. SERVS. (1982). https://archive.org/stream/reporttocongress00schw/reporttocongress00schw_djvu.txt.

88. Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(c)(1), 97 Stat. 65, 150 (codified as amended at 42 U.S.C. § 1395ww (2012)).

89. 42 U.S.C. § 1395ww(d)(1) (2012); Prospective Payments for Medicare Inpatient Hospital Services, 48 Fed. Reg. 39,752 (Sept. 2, 1983).

90. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6202, 103 Stat. 2106, 2234 (codified as amended at 42 U.S.C. § 1395u(b) (2012)).

91. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §§ 4101-12, 104 Stat. 1388-54 to -68 (codified as amended at 42 U.S.C. § 1395u(b) (2012)).

92. 42 U.S.C. § 1395hh(b) (2012).

93. See *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988).

that outside experts should participate in updating payment rates.⁹⁴ Congress created the Prospective Payment Assessment Commission as a congressional commission to oversee the rate setting process.⁹⁵ In 1986, Congress established another comparable commission to oversee the new physician payment system.⁹⁶ In 1997, Congress consolidated the two commissions into the Medicare Payment Advisory Commission (MedPAC) an independent Congressional agency.⁹⁷ Like its predecessors, the MedPAC is comprised of experts in the financing and delivery of health care services from the fields of economics, health policy, public health, and medicine. The commission advises Congress on all payments to all providers and health plans.⁹⁸

C. Adjudication under the Medicare Program in the Twentieth Century

The managers of the Medicare program, as benefit program managers, downplayed appeal procedures. Indeed, as discussed above, in 1965, there was no legal requirement to have appeal procedures because the Supreme Court had yet to rule that government benefits were constitutionally protected property interests.⁹⁹

1. Beneficiary Appeals

The original statute provided appeal procedures for Medicare beneficiaries under the Social Security Act.¹⁰⁰ When the Medicare Advantage program and voluntary prescription drug benefit were enacted, Congress established grievance procedures for these programs. All Medicare Advantage plans must have “meaningful procedures” to adjudicate beneficiary complaints with the health plan.¹⁰¹ For prescription drugs offered through Medicare Advantage plans, beneficiaries appeal disputes over drug cost and coverage to the plan’s appeal

94. *Hearings on the Hospital Prospective Payment System Before the Subcomm. On Health of the S. Comm. on Finance, Part I*, 98th Cong. 128, 135 (1983) (statement of J. Alexander McMahon, President, American Hospital Association).

95. Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(e), 97 Stat. 65, 152-53 (codified as amended at 42 U.S.C. § 1395ww(e)(2) (2012)); Eleanor D. Kinney, *Making Hard Choices Under the Medicare Prospective Payment System: One Administrative Model for Allocating Medical Resources Under a Government Health Insurance Program*, 19 IND. L. REV. 1151 (1986).

96. Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, § 9305, 100 Stat. 82, 190 (codified as amended at 42 U.S.C. § 1395w-1 (2012)).

97. Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4022, 111 Stat. 251, 350 (codified as amended at 42 U.S.C. § 1395b-6 (2012)).

98. MEDPAC, <http://www.medpac.gov/about-medpac/> (last visited Dec. 14, 2014).

99. See *supra* notes 43-44.

100. Social Security Amendments of 1965, Pub. L. No. 89-97, § 1869, 79 Stat. 286, 330 (codified as amended at 42 U.S.C. § 1395ff (2012)).

101. 42 U.S.C. §§ 1395w-22(f)-(g) (2012).

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process.¹⁰² Prescription drug plans must have a similar appeals process with comparable steps, timetables, and other characteristics for their fee-for-service Medicare beneficiaries.

In 1972, due to a high volume of appeals over physician services, Congress precluded administrative and judicial review for these disputes.¹⁰³ However, as physician services became more complex and more procedures were performed on an outpatient basis, Medicare beneficiaries, physicians, and other outpatient providers called for the establishment of administrative and judicial review for appeals under the Medicare Program.¹⁰⁴ In 1986, Congress expanded appeal rights for Medicare beneficiaries and established administrative and judicial review of Part B claims above a specified monetary level.¹⁰⁵

Also in 1986, pursuant to HCFA's request, Congress imposed significant limitations on judicial review of national coverage determinations.¹⁰⁶ Specifically, these limitations precluded judicial review of Medicare's national coverage determinations and procedural challenges to Medicare policy for failure to comply with Administrative Procedure Act rulemaking procedures. Further, an administrative law judge (ALJ) cannot review any HHS decision on whether a service or procedure is a covered benefit under the Medicare. Additionally, a reviewing court must remand a disputed coverage policy back to CMS for augmentation of the record before making a final decision on the validity of the policy. Congress justified these limitations on the fact that HCFA specifically solicited input from physicians and occasionally technology assessments in the Medicare coverage policy-making process.¹⁰⁷

Despite these changes, the Part B appeals process continued to be problematic. The Subcommittee on Administrative Law and Government Relations of the House Judiciary Committee held hearings on the appeals process.¹⁰⁸ The U.S. GAO criticized the process as unduly lengthy.¹⁰⁹ In the 1980s and early 1990s, both the Administrative Conference of the United States and the American Bar Association formally expressed concerns and recommended changes in the appeals

102. 42 U.S.C. §§ 1395w-101(f)-(h) (2012).

103. Social Security Amendments of 1972, Pub. L. No. 92-603, § 2990, 86 Stat. 1329, 1464 (codified as amended at 42 U.S.C. § 1395ff (2012)).

104. See, e.g., *Medicare Appeals Provisions: Hearings Before the Subcomm. on Health of the S. Comm. on Finance*, 99th Cong. 270 (1985) (statement of Alan P. Spielman, Executive Director of Government Relations, Blue Cross and Blue Shield Association).

105. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a), 100 Stat. 1874, 2037 (codified as amended at 42 U.S.C. § 1395ff(b) (2012)).

106. *Id.*

107. H.R. REP. NO. 99-1012, at 350-51 (1986).

108. *Adjudicatory Procedures of the Department of Health and Human Services: Hearings Before the Subcomm. on Admin. Law and Gov't Relations of the H. Comm. on the Judiciary*, 101st Cong. (1989).

109. *Statistics on the Part B Administrative Law Judge Hearings Process*, U.S. GEN. ACCT. OFF. (1989), <http://gao.gov/assets/220/211946.pdf>.

process.¹¹⁰

In 2000, Congress enacted major changes in the Medicare appeal process, primarily in response to the concerns of medical device manufacturers.¹¹¹ This legislation consolidated the beneficiary appeals processes for Parts A and B and mandated major reforms such as strict deadlines to expedite the process.¹¹² This legislation also established an expedited review process for Medicare coverage determinations for beneficiaries with an immediate need for the service without raising it in the context of a claim.¹¹³ This legislation also established “qualified independent contractors” to conduct reconsiderations of contractors’ initial determinations or redeterminations. These contractors are independent of any existing Medicare contractors that make initial determinations and are comprised of panels of physicians and other health care professionals.¹¹⁴

In the Medicare Modernization Act of 2003, Congress made additional reforms to the Medicare appeals process. Specifically, the act established expedited judicial review for beneficiaries and, remarkably, the beneficiaries’ providers or suppliers. Expedited review may occur when the ALJ or other adjudicator determines that no material facts are in dispute and the HHS Departmental Appeals Board has no authority to decide the question of law or regulation relevant to the matters in controversy.¹¹⁵ This extraordinary provision accommodated the reality that suppliers of new medical devices and providers offering new medical technologies also have important and ongoing interests in disputed coverage issues.

Another problem addressed in the Medicare Modernization Act was the ALJs for Medicare appeals.¹¹⁶ CMS, and previously HCFA, maintained that the Social Security ALJs who heard Medicare appeals were too independent in reversing many determinations and did not appreciate the reality of escalating costs facing the Medicare program. Also, ALJs often disregarded HCFA manuals as well as

110. Recommendation 86-5, *supra* note 68; AM. BAR ASS’N, *supra* note 69.

111. Medicare, Medicaid, and SCHIP Benefits and Improvement Act (BIPA) of 2000, Pub. L. No. 106-554, §§ 521-22, 114 Stat. 2763, 2763A-534 to -547 (codified as amended at 42 U.S.C. §1935ff (2012)); see *Patient Appeals in Health Care: Hearings before the Subcomm. on Health of the H. Comm. on Ways and Means*, 105th Congress (1998).

112. 42 U.S.C. § 1935ff(b)(1)(A) (2012); see Office of Inspector Gen., *Medicare Administrative Appeals: The Potential Impact Of BIPA*, U.S. DEP’T HEALTH & HUM. SERVS. (2002), <http://oig.hhs.gov/oei/reports/oei-04-01-00290.pdf>.

113. 42 U.S.C. §§ 1395ff(f)(4)-(5) (2012); see The National and Local Coverage Determination Review Process for an Individual with Standing as Defined in Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protections Act of 2000, 66 Fed. Reg. 54,253 (U.S. Dep’t Health & Hum. Servs. Oct. 26, 2001) (notice of ruling).

114. 42 U.S.C. § 1935ff(g) (2012).

115. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, § 932, 117 Stat. 2066, 2399 (codified as amended at 42 U.S.C. § 1395ff (2012)).

116. 42 U.S.C. §§ 1395ff(b)(1)(B)-(C) (2012).

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local coverage determinations in their decisions because they were only bound by the law, legislative rules, and HCFA rulings. HCFA sought to create its own corps of administrative judges in an effort to attain perhaps inappropriate control over ALJ decisions.¹¹⁷

The Medicare Modernization Act required the transfer of the functions of ALJs hearing Medicare appeals from the Social Security Administration to HHS.¹¹⁸ The Medicare Modernization Act required that ALJs be located in an office organizationally and functionally separate from CMS that reports directly to the Secretary. The Secretary must also provide for an appropriate geographic distribution of ALJs throughout the U.S. to ensure timely access for beneficiaries. Today, Medicare appeal provisions are consolidated and integrated due to these reforms.¹¹⁹

The history of the Medicare appeals process for beneficiary appeals exhibits a pattern of resistance from HCFA in opening up the appeals process for examination by ALJs and courts. HCFA's attempt to substitute its own ALJs for the Social Security ALJs was somewhat heavy-handed and not in the spirit with administrative law principles such as separation of functions and judicial independence. As a result, Congress has had to step in over the years to reform the appeals process to make it conform to administrative law principles.

2. Provider Appeals

The Social Security Amendments of 1965 contain no provision for providers to appeal any determinations of the Medicare program. Providers objected to the informality of intermediary hearing proceedings and the lack of administrative and judicial review for the intermediary's final payment determination.¹²⁰ In 1972, a federal district court decision ruled that extant intermediary hearing procedures with no appeal to the Secretary violated providers' rights to procedural due process.¹²¹

Responding to these provider concerns and acknowledging that it had overlooked resolving provider disputes when originally designing the Medicare

117. Office of Inspector Gen., *Medicare Administrative Appeals: ALJ Hearing Process*, U.S. DEP'T HEALTH & HUM. SERVS. (Sept. 1999), <https://oig.hhs.gov/oei/reports/oei-04-97-00160.pdf>.

118. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 § 931 (codified as amended at 42 U.S.C. § 1395ff note (2012)); see Eleanor D. Kinney, *Changes in the Adjudication of Medicare Beneficiary Appeals in the New Medicare Prescription Drug Legislation: Reform or Retreat?*, ADMIN. & REG. L. NEWS, Spring 2004, at 6.

119. See CMS, *Medicare Appeals Process*, U.S. DEP'T HEALTH & HUM. SERVS. (Aug. 2014), <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedicareAppealsprocess.pdf>.

120. See Leonard Homer & Peter Platten, *Medicare Provider Reimbursement Disputes: An Analysis of the Administrative Hearing Procedures*, 63 GEO. L.J. 107, 111 (1974).

121. Coral Gables Convalescent Home, Inc. v. Richardson, 340 F. Supp. 646 (S.D. Fla. 1972).

appeals system,¹²² Congress established the PRRB in the Social Security Amendments of 1972 to adjudicate payment disputes arising between providers and intermediaries.¹²³ All institutional providers paid under Part A can appeal to the PRRB.¹²⁴ Congress also authorized judicial review of PRRB decisions.¹²⁵ Congress has also specified that physicians and other Part B providers can appeal payment determinations if the beneficiary has assigned the claim and agreed to be represented by the provider.¹²⁶

III. A CALAMITY IN MEDICARE ADJUDICATION

Today, the Medicare appeals system is swamped—mostly with provider appeals. One reason for the congestion is the large number of hospital appeals over decisions of contractors regarding Medicare admissions. The Medicare Modernization Act of 2003 established the recovery audit demonstration for the FFS Medicare providers to specifically test the idea of paying Recovery Audit Contractors on a contingency fee basis.¹²⁷ In 2006, Congress established the Medicare fee-for-service recovery audit program nationwide.¹²⁸ Section 6411 of the ACA expanded the recovery audit program to include Parts C and D of the Medicare program and the Medicaid program.¹²⁹ The U.S. GAO estimated that CMS and its recovery audit contractors recovered \$70 billion in improper

122. S. REP. NO. 92-1230, at 248 (1972).

123. Social Security Amendments of 1972, Pub. L. No. 92-603, § 243(a), 86 Stat. 1329, 1420 (codified as amended at 42 U.S.C. § 1395oo (2012)).

124. *Id.*

125. *Id.* (codified as amended at 42 U.S.C. § 1395oo(f) (2012)).

126. 42 U.S.C. § 1395ff(b)(a)(C) (2012).

127. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256; see Ctrs. for Medicare & Medicaid Servs., *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration*, U.S. DEP'T HEALTH & HUM. SERVS. (2008), <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/RACEvaluationReport.pdf>.

128. Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, § 302, 120 Stat. 2922, 2991 (codified as amended 42 U.S.C. § 1395ddd(h) (2012)).

129. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6411, 124 Stat. 119, 775 (2010) (codified as amended at 42 U.S.C. § 1395ddd(h) (2012)); see Ctrs. for Medicare & Medicaid Servs., *Medicare Claim Review Programs: MR, NCCI Edits, MUEs, CERT, and Recovery Audit Program*, U.S. DEP'T HEALTH & HUM. SERVS. (Jan. 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MCRP_Booklet.pdf; Abby Pendleton & Jessica L. Gustafson, *The Future of the Recovery Audit Contractor Program*, 7 A.B.A. HEALTH ESOURCE 12 (Aug. 2011), http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1108_pendleton.html.

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Medicare and Medicaid payments in FY 2010.¹³⁰

Recovery Audit Contractors (RACs) have focused extensively on the appropriateness of inpatient hospital admissions versus outpatient “observational” status in an inpatient hospital bed. Hospital admissions, paid for under Part A, cost the Medicare program more than hospital stays on “observational status” paid under Part B with considerable and often unexpected cost-sharing for beneficiaries.¹³¹ Also, three nights in the hospital under observational status do not count toward the requisite three days of inpatient hospitalization for subsequent admission covered to a skilled nursing facility due to the statutory provisions defining the benefit.¹³² In *Bagnall v. Sebelius*, the plaintiff unsuccessfully tried to convince a federal district court that observational status violated the Medicare statute.¹³³ CMS has sought to clarify the rules for distinguishing between observational status and admissions in a rule.¹³⁴

Nevertheless, a consequence of the recovery audit program has been a dramatic increase in the number of provider appeals before the Office of Medicare Hearing and Appeals (OHMA).¹³⁵ In congressional testimony, OMHA’s chief ALJ reported that OMHA would focus only on beneficiary appeals and postpone hearing provider appeals for several years.¹³⁶ Legislators are very concerned about

130. *Fraud Detection Systems: Centers for Medicare and Medicaid Services Need to Ensure More Widespread Use*, U.S. GOV’T ACCT. OFF. (June 2011), <http://www.gao.gov/assets/330/320854.pdf>.

131. See Zhanlian Feng et al., *Sharp Rise in Medicare Enrollees Being Held in Hospitals for Observation Raises Concerns about Causes and Consequences*, 31 HEALTH AFF. 1251 (2012); Mary D. Naylor et al., *Unintended Consequences of Steps to Cut Readmissions and Reform Payment May Threaten Care of Vulnerable Older Adults*, 31 HEALTH AFF. 1623 (2012); see also Office of Inspector Gen., *Hospitals’ Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries*, U.S. DEP’T HEALTH & HUM. SERVS. (July 2013), <https://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf>.

132. 42 U.S.C. § 1395d(a) (2012).

133. No. 3:11CV1703, 2013 WL 5346659 (D. Conn. Sept. 23, 2013).

134. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates, 78 Fed. Reg. 50,495, 50,906-54 (Aug. 19, 2013); see Andrew B. Wachler & Jesse A. Markos, *CMS’s Final Rule Regarding the Payment of Part B Inpatient Services and the Revised Standard for Hospital Inpatient Admissions*, 10 A.B.A. HEALTH ESOURCE 1 (Sept. 2013), http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1309_wachler.html.

135. See Judith A. Waltz, *Office of Medicare Hearings and Appeals: “Growing Pains” as Appeals Workload Increases to Record Levels*, 16 RAP SHEET 8 (2013).

136. *Office of Medicare Hearings and Appeals Workloads: Hearing Before the Subcomm. on Energy Policy, Health Care, & Entitlements of the H. Comm. on Oversight & Government Reform*, 113th Cong. 4 (2014) (statement of Nancy J. Griswold, Chief Administrative Law Judge, Office of Medicare Hearings and Appeals).

the congestion of appeals,¹³⁷ as is the AHA.¹³⁸ The major reason for the concern is that provider appeals will be delayed further as the OMHA focuses on beneficiary appeals.

CMS has offered to settle all claims for a fixed percentage. Specifically, on August 29, 2014, CMS announced a settlement with affected hospitals and health systems of sixty-eight percent of their so-called inpatient-status claims in the appeals process. CMS is offering this settlement pursuant to the Social Security Act and CMS's regulations regarding claims collection and compromise.¹³⁹ In return, providers have to withdraw all of their appeals.¹⁴⁰

There are alternative dispute resolution processes available in the federal government to streamline adjudicative procedures and get to settlement quicker. The Administrative Dispute Resolution Act of 1996 authorizes all agencies to use alternative dispute resolution (ADR), which might be invoked in the resolution of provider claims.¹⁴¹ This statute amends section 556 to authorize the use of ADR in formal hearings under sections 556 and 557 of the Administrative Procedure Act.¹⁴² According to the statute, "[a]n agency may use a dispute resolution proceeding for the resolution of an issue in controversy that relates to an administrative program, if the parties agree to such proceeding."¹⁴³ This act also identifies situations, such as when "a definitive or authoritative resolution of the matter is required for precedential value,"¹⁴⁴ where ADR should not be used.¹⁴⁵

The Administrative Dispute Resolution Act creates an interagency working group chaired by the Attorney General to promote the use of ADR across the federal government. The working group currently focuses on the following four

137. Paul Demko, *Legislators Decry Broken Medicare Payment Appeals Process*, MODERN HEALTH CARE (May 20, 2014), <http://www.modernhealthcare.com/article/20140520/NEWS/305209963/legislators-decry-broken-medicare-payment-appeals-process>.

138. Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass'n, to Marilyn Tavenner, Adm'r, Ctrs. for Medicare & Medicaid Servs., on Significant Delay in Assignment of Hospital Appeals to Administrative Law Judges (Jan. 14, 2014), <http://www.aha.org/advocacy-issues/letter/2014/140114-let-aljdelays.pdf>.

139. See 42 C.F.R. §§ 401.601, 401.613 (2011) (claims collection and compromise); 42 C.F.R. § 405.376 (2004) (compromise of overpayments).

140. Ctrs. for Medicare & Medicaid Servs., *Frequently Asked Questions: Hospital Appeals Settlement for Fee-For-Service Denials Based on Patient Status Reviews for Admissions Prior to October 1, 2013*, U.S. DEP'T HEALTH & HUM. SERVS. (2014), http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/HospitalAppealsSettlementFAQs_090814_508.pdf.

141. Administrative Dispute Resolution Act (ADRA) of 1996, Pub. L. No. 104-320, 110 Stat. 3870 (codified as amended at scattered sections of 5 U.S.C.).

142. *Id.* § 4 (codified as amended at 5 U.S.C. §§ 556(c)(7)-(8) (2012)).

143. 5 U.S.C. § 572(a) (2012).

144. *Id.* § 572(b)(1).

145. *Id.* § 572(b).

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areas: (1) workplace disputes, (2) contracts and procurement disputes, (3) regulatory enforcement disputes, and (4) claims against the government. RAC appeals involve matters similar to the last three categories and clearly would be appropriate candidates for ADR.

HHS has an ADR division with the DAB, which is associated with the interagency working group convened by Department of Justice. The services of this DAB ADR Division could be made available to resolve a body of appeals on a controversial issue such as RAC appeals by hospitals.¹⁴⁶ Of note, OMHA has launched a “Settlement Conference Facilitation Project” to resolve appeals.¹⁴⁷

Given that courts have firmly established that providers do not have a property interest in payment,¹⁴⁸ Congress and HHS have much more flexibility in designing expeditious dispute resolution procedures that would mitigate the congestion in provider appeals that the Medicare program is experiencing today. CMS might carefully consider how to design an inquisitorial system, for example, that would enable an examiner to review claims on paper with written input from providers and their counsel. Also, rules that more clearly establish criteria for inpatient admissions and observational stays would greatly help the adjudication process and reduce appeals.

Of interest, the recovery audit program appeals controversy arose as a result of Medicare behaving as a procurement program, seeking to control excessive vendors’ costs and profit seeking conduct. The fact that the Medicare program paid recovery audit contractors on a contingent fee basis is more consistent with Medicare as a procurement program. Certainly the use of a contingent fee payment system is not consistent with a truly collaborative relation that the CMS seeks to achieve with the shared savings program as described below.¹⁴⁹

As a government benefits program, procedural due process requires some kind of hearing when government takes adverse action against a beneficiary. The Medicare program, while not required, has accorded comparable hearing rights to health care providers. Because providers and suppliers do not have constitutionally protected property, CMS has great flexibility in designing dispute resolution procedures that will expedite the appeals process while being fair to providers.

146. *Alternative Dispute Resolution Division*, U.S. DEP’T HEALTH & HUM. SERVS., <http://www.hhs.gov/dab/divisions/adr/> (last visited Nov. 17, 2014).

147. Office of Medicare Hearings and Appeals, *Settlement Conference Facilitation Pilot: Fact Sheet*, U.S. DEP’T HEALTH & HUM. SERVS., (Aug 2014) http://www.hhs.gov/omha/OMHA%20Settlement%20Conference%20Facilitation/settlement_conference_facilitation_pilot_fact_sheet.pdf.

148. *See* St. Francis Hosp. Ctr. v. Heckler, 714 F.2d 872 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984); Geriatrics, Inc. v. Harris, 640 F.2d 262, 265 (10th Cir. 1981), *cert. denied*, 454 U.S. 832 (1981). In only one case, *Fischer v. United States*, and in dicta, did the Supreme Court even suggest otherwise. 529 U.S. 667 (2000).

149. *See infra* notes 154-161 and accompanying text.

IV. A SEA CHANGE IN MEDICARE RULE AND POLICY-MAKING

Historically, the Medicare program used a regulatory approach to control the utilization of health care services and improvement of the quality of services for Medicare beneficiaries. In 1972,¹⁵⁰ and again in 1981,¹⁵¹ Congress established medical peer review organizations with independent physicians to review Medicare utilization retrospectively. These programs were very unpopular with physicians.¹⁵² By the 1990s, HCFA concluded that these programs and their strategy of retrospective utilization review had been unsuccessful in identifying quality breaches or improving the quality of care.¹⁵³ At that point, HCFA determined to refocus the work of its peer review contractors on quality improvement only.¹⁵⁴ This development presaged a new conception of provider relations and collaboration that CMS pursued after 2000.

At the beginning of the new century, HHS policy makers inaugurated a sea change in their approach to providers. Under the Republican President and Congress, the approach moved from regulatory and controlling to collaboration between CMS and providers in addressing the issues of the cost and quality of medical care. Addressing fraud and abuse was a different matter, with the OIG having primary responsibility for enforcement of fraud and abuse law. The newly named Center for Medicare and Medicaid Services (from the Health Care Financing Administration) handles Medicare policy-making. The Medicare Modernization Act of 2003,¹⁵⁵ a Republican vision of what the Medicare program should be, implemented many complex and technical programs to improve quality and control costs. These programs marked a shift in how CMS viewed providers, now as colleagues in seeking to improve the quality of health care rather than as regulated parties.

150. Social Security Amendments of 1972, Pub. L. No. 92-602, § 249F, 86 Stat. 1329, 1429 (codified as amended at 42 U.S.C. §§ 1320c-1 to -19 (2012)).

151. Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Pub. L. No. 97-248, § 1151, 96 Stat. 324, 382 (codified as amended at 42 U.S.C. § 1320c (2012)).

152. JONATHAN OBERLANDER, *THE POLITICAL LIFE OF MEDICARE* 119 (2003).

153. See Anita J. Bhatia et al., *Evolution of Quality Review Programs for Medicare: Quality Assurance to Quality Improvement*, 22 HEALTH CARE FIN. REV. 69 (2000); Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900 (1992); Claire Snyder & Gerard Anderson, *Do Quality Improvement Organizations Improve the Quality of Hospital Care for Medicare Beneficiaries?*, 293 JAMA 2900 (2005).

154. Health Care; Medicare and Medicaid Programs; Peer Review Organizations: Name and Other Changes—Technical Amendments, 67 Fed. Reg. 36,539 (May 24, 2002) (to be codified at 42 C.F.R. pts. 4-5); see Elizabeth H. Bradley et al., *From Adversary to Partner: Have Quality Improvement Organizations Made the Transition?*, 40 HEALTH SERVS. RES. 459 (2005).

155. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

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There are many reasons why this sea change has occurred. Increasingly, hospitals and health care organizations are run by executives with training in business administration. The power of doctors over hospitals and their own practices has diminished as health services research has provided an empirical methodology to assess whether care is of high quality and/or too expensive. Also, younger physicians are more accepting of, or perhaps more accustomed to, the business approach to medicine so resisted by their predecessors.

Finally, the ACA has sealed the deal on the collaborative model for administering the Medicare program and making health policy.¹⁵⁶ Many of the programs are established with minimal guidance in the form of legislative rules and provide considerable space where providers can innovate so long as they meet cost and quality targets.

The Medicare Shared Savings program that establishes Accountable Care Organizations (ACO) is a case in point. This program facilitates coordination and cooperation among providers to improve the quality of care for fee-for-service Medicare beneficiaries. Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating and/or participating in an ACO.¹⁵⁷ The legislative history describes Congress' expectations for the program:

The ACO pilot program is designed to be flexible enough that a variety of physicians and other providers can participate. Many large, multispecialty group practices are well positioned to participate in the pilot program since most already provide integrated, coordinated care for their patients. The ACO pilot will recognize and reward efforts already underway by such groups, often in conjunction with hospitals, to provide efficient, high quality care. It will also allow providers to be rewarded for using advances in health information technology such as electronic medical records, telemedicine, and home monitoring equipment in ways that improve patient care. The Secretary should allow for the use of such technologies in order to facilitate coordinated, patient-centered care.¹⁵⁸

Moreover, the ACA provides that the Shared Savings Program will not be subject to oversight from the Office of Information and Regulatory Affairs in the Office of Management and Budget.¹⁵⁹ The Affordable Care Act accords the Secretary the authority to waive virtually any statutory requirement for the

156. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), *amended by* Health Care and Education Reconciliation Act (HCERA) of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

157. Shared Savings Program, CTRS. FOR MEDICARE & MEDICAID SERVS. (2014), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/>.

158. H.R. REP. NO. 111-443, pt. 1, at 417 (2010).

159. 42 U.S.C. § 1395jjj(e) (2012).

Medicare program.¹⁶⁰ Finally, section 3022 expressly precludes administrative and judicial review under the Medicare statute for the determinations set forth in Figure 2.¹⁶¹

FIGURE 2: DETERMINATIONS FOR WHICH ADMINISTRATIVE AND JUDICIAL REVIEW PRECLUDED

- The specification of criteria for ACOs.
- The assessment of the quality of care furnished by an ACO and the establishment of performance standards.
- The assignment of Medicare fee-for-service beneficiaries to an ACO.
- The determination of whether an ACO is eligible for shared savings and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO.
- The percent of shared savings specified by the Secretary and any limit on the total amount of shared savings established by the Secretary.
- The termination of an ACO.

The ACA has essentially cut off traditional mechanisms by which regulated parties seek redress from government overreaching. From a positive perspective, this limitation on remedies requires providers to resolve differences with CMS politically without recourse to courts. In a traditional regulatory regime with command and control regulation, denying access to judicial review would probably be inappropriate as an affected party would have no other recourse to correct an injustice. However, under the shared savings program, CMS has broad statutory parameters in which to operate and great flexibility to change policy. Consequently, there is space for providers to negotiate with CMS as in a business context to resolve differences. Further, CMS has exhibited a willingness to negotiate with providers in a productive manner.

This flexibility on the part of CMS is evident in the rule-making proceedings for the rules for the shared savings program. Program policy has primarily been made in program guidance and consultation with providers. CMS promulgated final rules to implement the program in November 2011.¹⁶² The text of the final

160. 42 U.S.C. § 1395jjj(f) (2012).

161. 42 U.S.C. § 1395jjj(g) (2012).

162. Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425); see Ctrs. for Medicare & Medicaid Servs *Summary of Final Rule Provisions for Accountable Care Organizations under the Medicare Shared*

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rule contains only two pages of text but has a long discussion of the comments submitted to the proposed rule. The preamble reads more like the minutes of a professional conference than a conventional preamble of a rule of a regulatory agency.

Although initially skeptical of ACOs,¹⁶³ the provider community has developed numerous ACOs with measured enthusiasm across the United States. One reason for provider participation may be how responsive CMS was in addressing provider concerns in the final rule for ACOs. Specifically, Dr. Donald Berwick, the former CMS administrator, has indicated that CMS made many changes in the final rules for ACOs to accommodate provider comments and facilitate provider participation.¹⁶⁴ One interesting report from an industry study is remarkably positive about ACOs and their initial accomplishments:

For many of us in the healthcare industry, the real potential game-changer in the Affordable Care Act was not the highly publicized provisions—the creation of insurance exchanges or its embrace of guaranteed issue, community rating, and regulated medical loss ratios. Rather, it was the way ACA opened the door to accountable care organizations (ACOs) in Medicare. Here at last was a development in US healthcare that would shift the focus to delivery and encourage provider organizations to compete on quality and price—something the traditional fee-for-service system has failed at rather spectacularly. We believed—and still do—that as this sort of competition is successfully introduced into the US system, it will inevitably spread, enabling and accelerating a movement toward healthcare that is priced and paid for in terms of value, not volume of services rendered.¹⁶⁵

In 2014, CMS issued a new proposed rule modifying the shared savings

Savings Program, U.S. DEP'T HEALTH & HUM. SERVS. (Nov. 2012), http://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/aco_summary_factsheet_icn907404.pdf.

163. Elliott S. Fisher & Stephen M. Shortell, *Accountable Care Organizations: Accountable for What, to Whom, and How*, 304 JAMA 1715 (2010).

164. Donald M. Berwick, *Making Good on ACOs' Promise: The Final Rule for the Medicare Shared Savings Program*, 365 NEW ENG. J. MED. 1753 (2011); see also Donald M. Berwick, *Launching Accountable Care Organizations: The Proposed Rule for the Medicare Shared Savings Program*, 364 NEW ENG. J. MED. e32 (Apr. 21, 2011), <http://www.nejm.org/doi/full/10.1056/NEJMp1103602>; Douglas Hastings, *The Medicare ACO Proposed Rule: Legal Structure, Governance, and Regulatory Sections*, HEALTH AFF. BLOG (Apr. 5, 2011), <http://healthaffairs.org/blog/2011/04/05/the-medicare-aco-proposed-rule-legal-structure-governance-and-regulatory-sections/>.

165. Niyum Gandhi & Richard Weil, *The ACO Surprise*, OLIVER WYMAN I (2012), http://www.oliverwyman.com/content/dam/oliver-wyman/global/en/files/archive/2012/OW_ENG_HLS_PUBL_The_ACO_Surprise.pdf; see Bruce Japsen, *Obamacare's Accountable Care Approach Reaches 1 in 10 In U.S.*, FORBES (Nov. 26, 2012, 9:00 AM), <http://www.forbes.com/sites/brucejapsen/2012/11/26/obamacares-accountable-care-approach-reaches-1-in-10-in-u-s/>.

program significantly based on the experience of the program in since its inception in 2012.¹⁶⁶ The CMS press release announcing the rule talked about CMS' desire to be collaborative:

The proposed rule reflects input from program participants, experts, consumer groups, and the stakeholder community at large. CMS is seeking to continue this important dialogue to ensure that the Medicare Shared Savings Program ACOs are successful in providing seniors and people with disabilities with better care at lower costs.¹⁶⁷

At this point in time, the program seems headed for success. The Shared Savings Program includes more than 330 ACOs in 47 states, providing care to more than 4.9 million beneficiaries in the Medicare fee-for-service program.¹⁶⁸ In the program's first year, 55 ACOs met the goals and earned shared savings payments of more than \$315 million and another 60 ACOs had reduced expenditures but not enough to earn shared savings.¹⁶⁹ The proposed rule contains extensive provisions to waive program requirements and other measures to create more flexibility to design care for Medicare beneficiaries that will reduce savings.¹⁷⁰

As an approach to achieving regulatory goals, this collaborative model is quite revolutionary especially since the model cuts off access to judicial review and other measures to protect the interests of regulated parties. If successful, it could have great relevance to the future of regulation.

CONCLUSION

Over the years, HHS and CMS have come to appreciate their roles as regulatory and procurement agencies when it comes to the administration of the Medicare program. But the history of the program suggests that HHS and CMS did not come easily to this realization. In the early years of the program, the

166. CMS, *Proposed Rule, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, U.S. DEP'T HEALTH & HUM. SERVS (2014), [http://www.ofr.gov/\(X\(1\)S\(tofvuj12vvyo3oiwkp3jkl3n3\)\)/OFRUpload/OFRData/2014-28388_PI.pdf](http://www.ofr.gov/(X(1)S(tofvuj12vvyo3oiwkp3jkl3n3))/OFRUpload/OFRData/2014-28388_PI.pdf); see *Fact Sheet: Proposed Changes to the Medicare Shared Savings Program Regulations*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 2, 2014), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-12-01.html>.

167. *Press Release: CMS Releases New Proposal to Improve Accountable Care Organizations*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 1, 2014), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-12-01.html>.

168. *Id.*

169. *Id.*

170. See sources cited *supra* note 166.

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managers of the Medicare program sought to control policy-making as well as appeal outcomes more than was appropriate. The best example of this development is Medicare coverage policymaking and the beneficiary appeals process.

Today, with respect to provider appeals, HHS and CMS have some flexibility to depart from evidentiary hearings in appeals and experiment with dispute resolution techniques that could expedite the appeals process. The back-up of recovery audit appeals discussed above demonstrates the need for expedition. Clearly, a more collaborative approach to approaching appeals is in order. The same kind of collaboration that CMS has exhibited with respect to ACOs could be brought to bear on resolving the calamity over recovery audit appeals. HHS and CMS now have the authority to use ADR procedures under Administrative Dispute Resolution Act and might well be advised to use them in the future. Of note, as this article goes to press, OMHA reports that it has cut the wait time for appeals of beneficiaries in half and deferring provider appeals.¹⁷¹

Finally, the more collaborative approach to policy-making and achieving regulatory goals, such as cost containment, are noteworthy. Since 2000, CMS has worked more collaboratively with providers to launch projects that engage the providers in the pursuit of common goals such as higher quality care at lower cost rather than the command and control approach to cost containment of earlier generations. If successful, this type of collaboration may be useful in other reform efforts for the health sector.

171. Susan Jaffe, *Seniors' Wait For A Medicare Appeal Is Cut In Half*, KAISER NETWORK NEWS (Dec. 23, 2014), <http://kaiserhealthnews.org/news/seniors-wait-for-a-medicare-appeal-is-cut-in-half/>.

